

July 1986

# ALLERGIC AND INFECTIOUS DISEASE RESEARCH

Prepared by the Office of Research Reporting and Public Response  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health      Public Health Service  
U. S. Department of Health and Human Services  
Telephone: 301-496-5717

## ELISA SENSITIVITY IN EARLY HTLV-III/LAV INFECTION

The enzyme-linked immunosorbent assay (ELISA) kits vary widely in their ability to detect the antibodies produced during early infection with the virus that causes Acquired Immunodeficiency Syndrome (AIDS), according to a study reported by Alfred J. Saah, M.D., National Institute of Allergy and Infectious Diseases, and colleagues at several institutions participating in a long-term AIDS research project. Since the ELISA kits were licensed in March 1985, they have been used routinely to screen donated blood.

Dr. Saah and his colleagues analyzed results of tests conducted on the blood of participants in a prospective study of 4,955 initially healthy, homosexual and bisexual males in four cities. The ongoing study, known as the Multicenter AIDS Cohort Study (MACS), is designed to trace the natural history of infection with HTLV-III/LAV virus in these men. Participants in the study are seen every six months, and blood specimens are collected at each visit.

Serological testing of the entire cohort was conducted using various commercially available ELISA kits and Western blot tests. The Western blot is normally used by blood collection agencies to confirm positive results of the ELISA. The investigators found discrepancies in the reactivity of some blood specimens when they were tested with various ELISA kits.

Dr. Saah reported that comparison of the data revealed that some blood specimens identified as antibody-negative by certain kits were antibody-positive when tested with kits from different manufacturers and with Western blots.

The Western blots showed that these specimens contained antibodies to core proteins (gag gene products) of HTLV-III/LAV and frequently lacked antibodies to envelope proteins (env gene products). Antibodies to core proteins are often the first antibodies that develop during early infection with the virus.

Of 30 specimens that were positive for core-antibody only, kits from Bionetics identified 2, Electronucleonics 4, Abbott 13, DuPont 25, and Genetic Systems 25.

Tests of subsequent specimens showed increased production of antibodies to both core and envelope proteins, reflecting a true infection with the AIDS virus. The ELISA kits of all manufacturers identified these later specimens with greater accuracy.

(more)

(2)

While acknowledging that all homosexual and bisexual males have been advised to refrain from donating blood, Dr. Saah said that it is not possible to measure the effects of this advisory. "It is now apparent that a certain proportion of potential [blood] donors with very early infection lack sufficient levels of antibody to envelope proteins and thus will be missed by all of the currently licensed test kits," Dr. Saah said. "Sensitivity of the ELISA kits to core protein antibodies should be enhanced."

Dr. Saah presented his report to the National Institutes of Health Consensus Development Conference on "Impact of Routine HTLV-III Antibody Testing on Public Health," July 7-9, 1986. Principal authors of the study also include: B. Frank Polk, M.D., Homayoon Farzadegan, Ph.D., and Robin Fox, M.S., The Johns Hopkins University School of Hygiene and Public Health; John L. Fahey, M.D., and Parunag Nishanian, Ph.D., University of California, Los Angeles; Charles R. Rinaldo, Ph.D., University of Pittsburgh Graduate School of Public Health and School of Medicine; and John Phair, M.D., Howard Brown Memorial Clinic, Northwestern University Medical School.

# # #